K122989

BIOMET SPINE

OCT 24 2012

510(k) Summary

Preparation Date:	September 24, 2012
Applicant/Sponsor:	Biomet Spine (aka EBI, LLC) 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Margaret F. Crowe, Regulatory Affairs Project Manager Phone: 973-299-9300, ext. 2260 Fax: 973-257-0232
Trade name:	Biomet Lateral Spacer System
Common Name:	Non-cervical spinal spacer Vertebral body replacement
Classification Name:	Intervertebral body fusion device, 21 CFR §888.3080 Spinal intervertebral body fixation orthosis, 21 CFR § 888.3060
Device Panel /Product Code:	Orthopedic MAX Orthopedic MQP

Device Description:

The purpose of this submission is the introduction of a new device for intervertebral body fusion and vertebral body replacement. The Biomet Lateral Spacer System is constructed of medical grade Polyetheretherketone (PEEK-Optima LT1 per ASTM F-2026) and tantalum (per ASTM F-560) radiographic markers, and is available in multiple lengths/widths/heights and lordotic angles to meet varying patient anatomies.

Indications for Use:

The Biomet Lateral Spacer System is indicated for vertebral body replacement and intervertebral body fusion. When used for vertebral body replacement, the Biomet Lateral Spacer System is indicated for use in the thoracolumbar spine (i.e., T1- L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Biomet Lateral Spacer System is also indicated for treating fractures of the thoracic and lumbar spine. The Biomet Lateral Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. When used for vertebral body replacement, the Biomet Lateral Spacer System is designed for use with bone graft and is intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.

As an intervertebral body fusion device, the Biomet Lateral Spacer System is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1

BIOMET SPINE

spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. When used as an intervertebral body fusion device, the Biomet Lateral Spacer System is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The Biomet Lateral Spacer System may be implanted via an open or minimally invasive lateral approach.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the Biomet Lateral Spacer System is the same as, or similar to, the predicate devices. Examples of predicate devices include:

- Expandable PEEK Implant (K082406, K040928)
- ESL Spacer (K092574, K040482)
- Zyston Straight Spacer System (K112014)
- Zyston Curve Spacer System (K110650)
- Medtronic Clydesdale Spacer (K083026, K113528)
- NuVasive CoRoent (K071795)
- Synthes Spine Oracle Spacer (K072791)
- DePuy Lateral Spacer (K082128, K090899)

Performance Data

Mechanical testing recommended in the special controls guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was conducted. The testing conducted, along with the ASTM standard, are listed below:

1) Static Axial Compression (ASTM F-2077)
2) Dynamic Axial Compression (ASTM F-2077)
3) Static Compression-Shear (ASTM F-2077)
4) Dynamic Compression-Shear (ASTM F-2077)
5) Subsidence (ASTM F-2267 and ASTM F-2077)

Additional mechanical testing recommended in the special controls guidance document entitled "Guidance for Industry and FDA Staff: Spinal System 510(k)s" was conducted. The testing conducted, along with the ASTM standard, are listed below:

1) Static Torsion (ASTM F-2077)
2) Dynamic Torsion (ASTM F-2077)
3) Expulsion (ASTM Draft F-04.25.02.02)

Mechanical testing shows that the mechanical strength of the subject device is sufficient for the intended use.

K122989

BIOMET SPINE

Substantial Equivalence:

The Biomet Lateral Spacer System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. The predicates listed above are distributed for similar indications, and have similar design features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomet Spine (AKA EBI, LLC)
% Ms. Margaret F. Crowe
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

OCT 2 4 2012

Re: K122989
Trade/Device Name: Biomet Lateral Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: September 25, 2012
Received: September 26, 2012

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122989

Indications for Use

510(k) Number (if known): K122989

Device Name: Biomet Lateral Spacer System

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Prescription Use **X** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122989